REMARKS

At the outset, Applicants would like to thank Examiner Hughes and Examiner Henley for their time and consideration of the above-identified application during the interview with the undersigned on April 15, 2009. During the interview, the issues raised in the outstanding Official Action were discussed.

Claims 1-10, 13-22, and 35-37 are pending in the application.

Claims 1-10 and 13-22 have been amended to address formal matters raised in the outstanding Official Action.

Claim 1 has also been amended to recite that the claimed soft gelatin capsule comprising Type A gelatin exhibits a longer shelf life as compared to a soft gelatin capsule comprising Type B gelatin. Support for this recitation may be found in the present specification at page 11, lines 7-14 and in original claims 26 and 27.

New claims 35-37 have been added. Support for new claims 35-37 may be found in original claims 26 and 27 and in the present specification at page 5, lines 1-5; page 9, lines 1-5; and page 11, lines 7-14.

Claims 1-10, 13-22, 25, 30 and 31 are rejected under 35 U.S.C. 103(a) as allegedly being obvious over U.S. Patent No. 5,502,077 in the name of BREIVIK et al. (BREIVIK) and US. Patent No. 4,935,243 in the name of BORKAN et al. (BORKAN). Applicants believe that the present Amendment obviates this rejection.

The proposed combination of BREIVIK and BORKAN fails to disclose or suggest the claimed soft gelatin capsule containing Type A gelatin. BREIVIK discloses a soft

gelatin capsule containing a formulation comprising *ethyl esters* (see abstract), whereas BORKAN discloses a chewable, edible soft gelatin capsule (col. 3, lines 20-35). Neither publication suggests a soft gelatin capsule comprising Type A gelatin that contains a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form.

There is certainly no recognition in either reference of a soft gelatin capsule comprising Type A gelatin as claimed that exhibits a longer shelf life as compared to a soft gelatin capsule comprising Type B gelatin (see claim 1). Applicants also note that new claims 36-37 recite a gelatin "consisting essentially of" Type A gelatin (see page 9, lines 1-5 of the present specification). Claims 36 and 37 exclude gelatins that contain amounts of Type B gelatin (i.e., gelatin formed with an alkali pre-treatment) that would materially affect the shelf life of the capsule. Neither BREIVIK nor BORKAN disclose or suggest such features.

The Official Action contends that it is well known in the art that "Type A gelatin and Type B gelatin formation are both by the same process". The Official Action cites to US. Patent No. 4,935,243 in the name of BORKAN et al. (BORKAN) in support of this position. However, a careful reading of BORKAN at col. 3, lines 20-35 indicates that Type A gelatin and Type B gelatin are produced by different processes. Type A gelatin is produced with an acid process, whereas Type B gelatin is produced with an alkaline process. BORKAN also teaches that each type of gelatin has a different isoelectric point.

At column 3, lines 39-44, BORKAN states that "The gelatin may be of Type A,

Type B, or a mixture thereof. Bloom numbers, the indicator of gelatin strength, may range from about 60-300." Thus, BORKAN teaches that any type of gelatin may be used so long as the bloom strength is in a certain range. In this regard, one skilled in the art would not have expected Type A gelatin to behave differently from Type B gelatin, especially since the chemical structure of the two types of gelatin is essentially the same.

However, the inventors of the present application have unexpectedly discovered for the first time that Type B gelatin is surprisingly susceptible (and significantly more susceptible than Type A gelatin) to interaction with omega-3 polyunsaturated fatty acids, forming reactive oxidative decomposition products such as alcohols, aldehydes and ketones. In this regard, the Examiner's attention is respectfully directed to page 3, line 26 to page 4, line 15 of the present specification, wherein it is explained that the interaction of Type B gelatin with free omega-3 polyunsaturated fatty acids results in an unexpected increase in the rate of "aging" of the capsules. Applicants attribute this surprising finding to the fact that Type A and Type B gelatin are prepared by different techniques as explained above.

Applicants maintain that Table 1 on page 10 of the present specification provides evidence that the claimed invention exhibits unexpected results. Table 1 compares the stability of gelatin capsules prepared with Type A gelatin relative to Type B gelatin. The results indicate that, for the Type B gelatin capsules stored at a given temperature, there is a general increase in disintegration times as the storage time or temperature increases. These results stand in contrast to capsules prepared with Type A gelatin,

which exhibit improved disintegration times and shelf life when subjected to the same conditions as capsules prepared with Type B gelatin. In particular, the examiner's attention is respectfully drawn to the disintegration results for the Type B (bovine) gelatin capsules stored at 30°C for 12 months and at 40°C for 3 months and 6 months, as these capsules were shown to be insoluble. The corresponding Type A gelatin capsules took no more than 10 minutes to dissolve.

The Examiner is respectfully reminded that the Patent Office must consider objective indicia of nonobviousness whenever present. Specifically, the Patent Office is bound to consider evidence of unexpected results, commercial success, long-felt but unresolved needs, failure of others, skepticism of experts. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 f. 2d 1530, 1538 (Fed Cir. 1983). Federal Circuit precedent mandates consideration of evidence already present in the specification which is intended to illustrate the claimed invention in reaching a conclusion with regard to the obviousness of the claims. *In re Margolis*, 785 F. 2d 1029 (Fed Cir. 1986). (Vacating Board decision which refused to consider data in the specification which compared an embodiment of the invention with the prior art product and noting that such evidence spoke to unexpected results and non-obviousness).

Thus, contrary to what the Official Action contends that one skilled in the art would have expected, the results in the specification confirm that the use of a capsule comprising Type A gelatin and containing a formulation comprising omega-3 polyunsaturated fatty acids in free acid form unexpectedly provides a soft gel capsule having improved shelf stability and disintegration times.

In view of the above, Applicants respectfully submit that the proposed combination of BREIVIK and BORKAN fail to render obvious the claimed invention. Applicants respectfully request that the obviousness rejection be withdrawn.

Claims 1-10 and 13-22 are rejected on the grounds of nonstatutory obviousness-type double patenting as allegedly being unpatentable over claims 1-12 and 17 of United States Patent No. 5,792,795 ('795 patent). Applicants believe that the present Amendment obviates this rejection.

Claims 1-12 and 17 of the '795 patent neither disclose nor suggest a soft gelatin capsule containing Type A gelatin. While claim 11 of the '795 patent recites a gelatin capsule, there is simply no suggestion to use Type A gelatin.

Claim 1 is even further distinguishable from claims 1-12 and 17 of the '795 patent in that claim 1 recites that "the soft gelatin capsule exhibits a longer shelf life as compared to a soft gelatin capsule comprising Type B gelatin, said capsule containing a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form". Claims 36-37 are further distinguishable from the claims of the '795 patent as claims 36-37 recite a gelatin "consisting essentially of" Type A gelatin. There is also no recognition of the unexpected results exhibited by the claimed invention as discussed above. As none of the claims of the '795 patent disclose or suggest such features, applicant respectfully submit that independent claims 1, 36, and 37 (along with dependent claims 2-10 and 13-22) can not be obvious in view of the claims of the '795 patent. Applicants most respectfully request that the obviousness-type double patenting rejection be withdrawn.

In view of the present amendment and foregoing remarks, therefore, Applicants respectfully submit that the present application is in condition for allowance at the time of the next Official Action.

Respectfully submitted,
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